

acceptable salt thereof in an amount selected from 100 µg/ml to 100 mg/ml and 0.5% to 40% wt/wt and (ii) a pharmaceutical excipient which increases the solubility of the fexofenadine or salt in water, which is adapted for delivery of the fexofenadine or pharmaceutically acceptable salt thereof to the eye or nose.

24. (New) The composition as claimed in claim 23, wherein the pharmaceutical excipient is a water miscible, non-aqueous solvent.

25. (New) The composition as claimed in claim 24, wherein the solvent is selected from propylene glycol and glycofurool (tetraglycol).

26. (New) The composition as claimed in claim 23, wherein the pharmaceutical excipient is a material which is able to complex with the fexofenadine or pharmaceutically acceptable salt thereof.

B2  
cont.  
Sub C2

27. (New) The composition as claimed in claim 23, wherein the pharmaceutical excipient is a cyclodextrin.

28. (New) The composition as claimed in claim 23, which further comprises a gelling agent or a bioadhesive material.

29. (New) The composition as claimed in claim 28, wherein the gelling agent or bioadhesive material is selected from the group consisting of pectin, alginate, starch, gellan, chitosan, and a block co-polymer.

Sub C3

30. (New) The composition as claimed in claim 1, which further comprises a material that provides for controlled release of the fexofenadine or a pharmaceutically acceptable salt thereof.

31. (New) A method of treating a patient in need of a treatment with fexofenadine or a pharmaceutically acceptable salt thereof, the method comprising administering

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*B2*  
*conceded*

an effective amount of the composition according to claim 23 to a patient in need of such treatment.

32. (New) A method of treating rhinitis, the method comprising administering an effective amount of a composition according to claim 23 to a patient in need of such treatment.

33. (New) A method of treating a patient with a controlled release dose of fexofenadine or a pharmaceutically acceptable salt thereof, the method comprising administering an effective amount of a composition according to claim 30 to a patient in need of such treatment.

### REMARKS

Claims 1-14 and 20-33 are pending in the application. Claim 1 has been amended, and new claims 23-33 have been added. No new matter is added by the amendment or new claims. Support for the amendment and the new claims is found at least in the specification at page 3, lines 17-19, page 4, lines 11-14, and claims 1-22 as originally filed.

In accordance with 37 C.F.R. § 1.121, a marked-up version of claim 1, showing the changes made, is provided herewith.

In Paper No. 7, the Examiner rejected claims 1-4, 9-20, and 22 and objected to claims 5-8 and 21.

### Applicants' Invention

The invention is a composition containing fexofenadine or a pharmaceutically acceptable salt thereof. Specifically, the composition consists essentially of (i) fexofenadine and a pharmaceutically acceptable salt thereof and (ii) a pharmaceutical excipient that *increases the solubility of fexofenadine or its salt in water*. Alternatively, the composition of the invention includes (i) a specific amount of fexofenadine a pharmaceutically acceptable salt thereof and (ii) a pharmaceutical excipient that *increases the solubility of fexofenadine or its salt in water*. The pharmaceutical carriers of the invention are not generic carriers/vehicles, but are instead specific carriers which have as an identifying characteristic that they increase the solubility of fexofenadine or its salt in water. Such characteristic is specific, a functional definition of the molecular structure(s) included in the carrier, is not an "intended use" and therefore must be